REMARKS

This is responsive to the office action mailed December 14, 2007. Claims 1-15, 19, 21-28, 39, 49, 51-59 and 73-81 remain pending in the referenced patent application.

Applicants initially note that the Examiner has confirmed that the specification teaches how to make compound recited within claim 73, namely N, O, β, β-tetramethyl-L-tyrosyl-N^1-[(1S,2E)-3-carboxy-1-isopropyl-2-butenyl]-N^1,3 dimethyl-L-valinamide, at lines 20-26 of Example 57.

The Examiner states that the specification fails to teach how to use the elected compound. The Examiner goes on to state that there is inadequate disclosure for how to treat, inhibit or eradicate tumors with the elected compound. Applicants disagree.

Applicants reiterate here, and the Examiner has not argued otherwise, that experimentation that is not undue experimentation does not prevent foreclose enablement under the patent law. As the Examiner has correctly noted several time in the course of the prosecution of the instant application, the so-called Wands factors are relevant to determining what constitutes a permitted level of experimentation. Touching on the more relevant of the Wands factors, the nature of the invention is a method of treating a chemotherapeutic agent resistant tumor using a small molecule chemotherapeutic agent comprising a narrow and well defined core structure, for instance the Example 57 compound. There is agreement that the synthesis of the elected species is disclosed in great detail and therefore enabled, and that the level of skill in the art is very high. Moreover, the experimentation required to establish the usefulness of a particular compound is described in exquisite detail in connection with the Example 129 compound at, *inter alia*, pages 106 through 125 of the specification. *In vivo* data relating to the Example 57 compound, and many other compounds, are provided in Tables 11 and 12 at pages 127-137 of the specification.

At page 6 of the office action, first full sentence, the Examiner appears to be convinced that the use of the Example 129 compound to treat tumors is enabled. Applicants agree, and it is understood that the Examiner's position is likely based on the extensive experimentation relating to Example 129 at pages 106 through 125 of the specification. The Examiner, however, has thus far declined to extend the teachings of the specification to other compound, specifically the Example 57 compound, to find enablement for tumor treatment.

The Examiner is very respectfully requested to reconsider this position. It is initially noted that the Example 129 and Example 57 structures are identical except for the inclusion in Example 57 compound of a methoxy at the para position on the phenyl group. Thus, biological property similarities to the Example 129 compound are likely. Further, the Experimental procedures described at pages 106 through 125 for the Example 129 compound provide a road map for the experimentation required to more fully establish the chemical and biological properties of the Example 57 compound, and related claimed compounds. In view of this disclosure, the amount of experimentation required to confirm usefulness in tumor treatment for a particular claimed compound is both routine and relatively modest in scale. That is, a skilled chemist need only follow the provided experimental procedures substituting the compound of interest, for instance the Example 57 compound. The skilled chemist will not expend valuable time and effort devising new experimentation since a full experimental scheme is provided.

The Examiner mentions, at pages 3-4 of the instant office action, that the specification allegedly lacks sufficient *in vivo* data. As Applicants have previously argued, clinical data, or even *in vivo* animal data, is not required, either under the law or pursuant to any USPTO rules or guidance, to establish enablement. Nevertheless, Applicants appreciate that relevant tumor treatment data would tend to enhance the Examiner's level of confidence in the connection between the claimed method of using the Example 57 compound and "real world" tumor treatment, including tumor inhibition and/or eradication. Therefore, in order to address what Applicants believe are the Examiner's concerns, attached hereto an Affidavit from Frank Loganzo, Jr.which further establishes the nexus between activity at the cellular/receptor level and real world tumor treatment. As presented in the Affidavit, the Example 57 compound effectively inhibited the growth of several different human tumor types when grown as subcutaneous tumors in athymic mice. "Cures" were observed upon treatment of the Example 57 compound in this tumor model at certain dosage levels.

Applicants respectfully ask the Examiner to reconsider the enablement rejection in view of the arguments hereinabove and allow the claims.

The Examiner states that the specification discloses no astonishing results in connection with the claim 73 compound. Applicants note that "astonishing" results are nowhere required in the patent law relating to enablement. If the Examiner is referring to unexpected or surprising results necessary to achieve non-obviousness, Applicants point out that a rejection under 35 USC §103 has not been made in this application. Applicants will respond to any such rejection appropriately when it is received.

Applicants note that the Examiner has not reiterated his rejection of the terms "inhibiting" and "eradicating" under 35 USC §112, first paragraph. Although not stated explicitly in the office action, Applicants understand this to mean that the rejection of the use of these terms under 35 USC §112, first paragraph is withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of all pending rejections, and prompt issuance of a Notice of Allowance.

If any issues remain after consideration of this Amendment, the Examiner is urged to contact the undersigned by telephone at 845-602-4760.

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